Public Health Service



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration 555 Winderley Place, Suite 200 Maitland, Florida 32751

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Ref: Customs Entry Nos. DP3-0008425-9 & DP3-0008428-3

Product: Root & Tuber Vegetables

WARNING LETTER

FLA-98-40

April 6, 1998

Ms. Lucia Pall
The Herbal House
7513 N.W. 55th Street
Miami, Florida 33166

Dear Ms. Pall:

The Food and Drug Administration (FDA) requested to examine two shipments of root and tuber vegetables offered for entry into the United States by your firm on January 6, 1998, under the above referenced entry numbers, and determined that these shipment were not available for FDA examination. Regulation 1.90, Title 21, Code of Federal Regulations, (21 CFR 1.90) requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We requested the U. S. Customs Service (Customs) to order redelivery of these shipments (copies enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation.

Ms. Lucia Pall Page 2 March 25, 1998

Your written reply should be addressed to the Food and Drug Administration, Attention: Benjamin L. England, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

Douglas D. Tolen

Director, Florida District

Enclosure

cc: District Director

U. S. Customs Service

P. O. Box 52-3215

Miami, Florida 33152-3215

CBI Customs Brokers, Inc. 2550 N.W. 72nd Avenue

Ste. 309

Miami, Florida 33122